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Regulatory Proposal

PRO2010-01

Requirements for Designing Peel-Back and Multi-Component Labels of Domestic Class Pest Control Products

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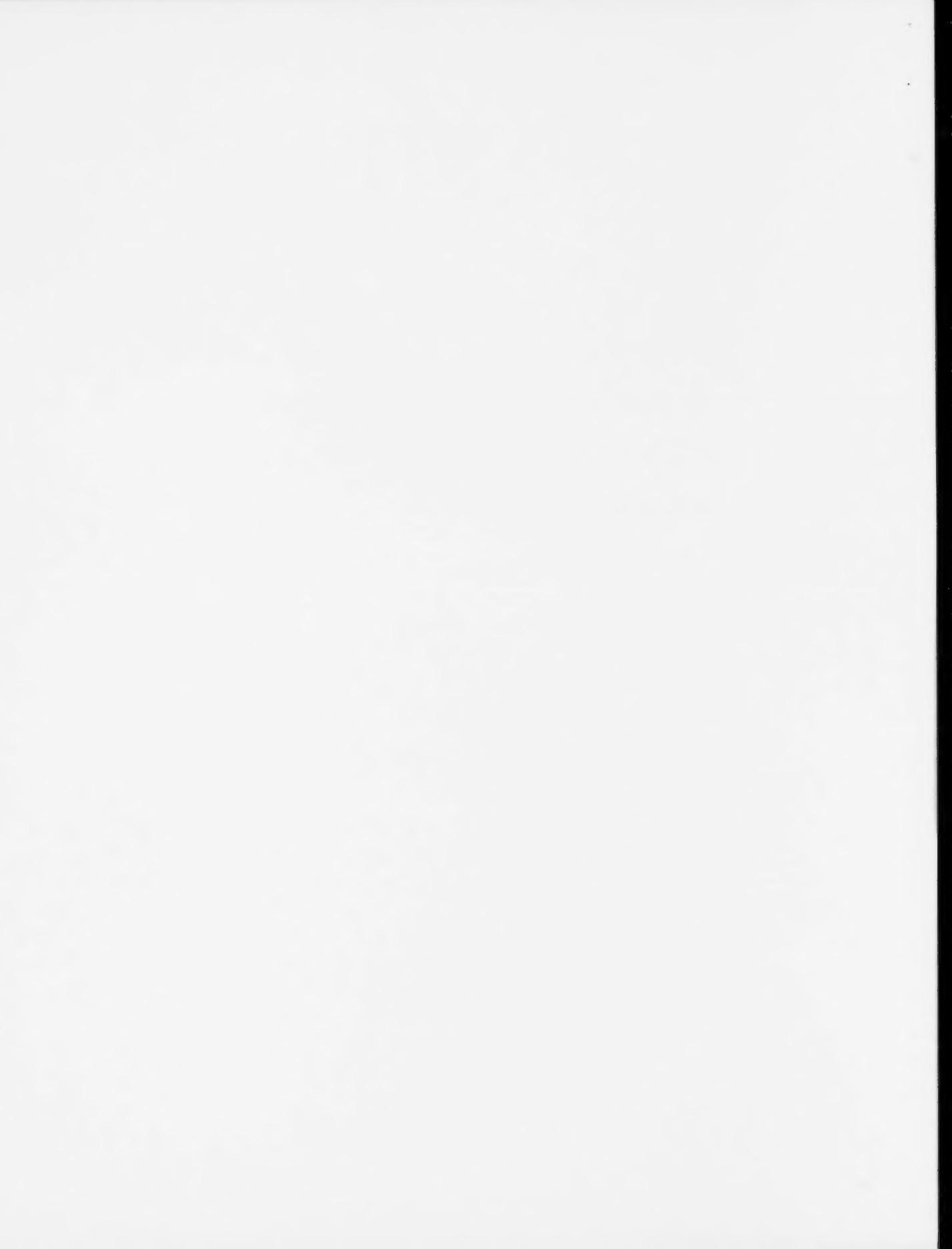
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This proposal is being distributed for information and comments. The PMRA will accept written comments from the public on the proposed guidance to improve statements on pest control product labels up to 90 days of publication of this document.

To assist in undertaking an effective consultation, please consider the following when preparing your feedback:

- Explain your views as clearly and as concisely as possible.
- Be sure to distinguish between what you support and what you object to in the proposal.
- Provide the rationale for your views and concerns, and whenever possible support these with facts, data or specific examples.
- Offer alternative wording or approaches.
- Describe any assumptions that you used.
- If you have concerns regarding the potential burden of costs of implementing the proposal or certain aspects of it, please provide: specific information about the nature of those burdens and costs; an estimate of the costs; an explanation of how you arrived at the estimate; and any suggestions for how costs could be reduced.
- Provide copies of any technical information or data you used in your comments.

Send your written comments by e-mail, fax or regular mail to Publications (see contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on these proposed requirements for designing peel-back and multi-component labels of Domestic Class pest control products.

1.0 Background

Pest control products that fall under the jurisdiction of the *Pest Control Products Act* must bear a label with principal and secondary display panels. Labels include anything that conveys information required under the Act or the Pest Control Products Regulations and include stickers, tags, seals, leaflets, brochures and wrappers applied or attached to packages.

Under the Pest Control Products Regulations, all aspects of every control product's label, including the nature of the label, its contents and location of information, are subject to the Minister's approval. Along with the Minister's authority to approve all labels goes a responsibility to be satisfied that a label is appropriate in all respects to convey information to protect human health, safety and the environment.

The Regulations describe what information is required on a label and require that the information be presented in a manner that is clearly legible and indelible. However, due to additional labelling requirements for pest control products, it is becoming increasingly difficult for registrants to maintain label legibility, primarily on Domestic Class products. Appendix I contains a glossary of terms related to labelling.

2.0 Introduction

With requirements for additional label information arising out of initiatives such as bilingual labelling and recommendations to improve the presentation of risk-reduction information (for example, more white space, boxed text) registrants have commented that this will place greater demands on product label space, possibly resulting in increased numbers of peel-back labels in the future.

Although peel-back ("crack n' peel" style) labels allow increased space for label text, the United States Environmental Protection Agency Consumer Labelling Initiative revealed that consumers are generally reluctant to open peel-back labels in the store to read the entire label. In Canada, concerns were expressed about the lack of instructions directing readers to additional information under the peel-back label. Additional concerns were raised over the possibility of peel-back labels becoming detached from the product container or having precautions, first aid and disposal statements obscured by the peel-back portion of the label.

The proposed requirements are based on an analysis of the issues and similar requirements for product labelling found in Canada's *Consumer Chemicals and Containers Regulations, 2001*; the United States Environmental Protection Agency's *Label Review Manual* (2003); and the Pesticides Safety Directorate *Labelling Handbook* (2002, amended 2004) in the United Kingdom. Requirements for small container labels on drugs in Canada's Food and Drug Regulations and United States Environmental Protection Agency Federal Register were also considered.

Based on the issues identified and the legal authority pertaining to labelling, the PMRA is proposing these criteria and design requirements for peel-back and multi-component labels of Domestic Class pest control products to ensure that information to protect human health, safety and the environment is conveyed in a reasonable manner and that registrants are treated in a consistent manner. The criteria for determining when this document can be used or when a product can be subject to this document is proposed in Appendix II.

2.1 Regulatory Requirements for Peel-Back and Multi-component Labels

When the conditions of registration indicate that in order to present the information required on the principal and secondary panels, a brochure or leaflet may be required. Section 28(2) of the Pest Control Products Regulations states that:

- the principal display panel must have prominently shown on it the statement "READ ATTACHED BROCHURE (or LEAFLET) BEFORE USING"; and
- the brochure or leaflet must contain all of the information that is to be shown on the principal and secondary display panels.

Brochures and leaflets can refer to the outer packaging to which small containers are attached.

Canada's Food and Drug Regulations allow for both inner and outer labelling. When the container of a drug is too small to accommodate an inner label that conforms to the requirements, the outer label must contain all the information required by these Regulations.

Similarly when small containers of pest control products are affixed to outer packaging, the outer packaging must contain all of the information that is required on the principal and secondary display panels.

3.0 Additional Requirements for Peel-back Labels

3.1 Durability and Integrity

The PMRA is proposing requirements to address concerns that peel-back labels may become detached from the product container. Domestic Class pest control products with peel-back labels would need to conform to the following:

- Under normal use, peel-back labels must be:
 - resealable;
 - able to withstand repeated openings and closings without detaching itself from the product container; and
 - able to withstand moisture without detaching from the product container.
- Any peel-back label with three or more pages must be numbered to indicate the total number of pages (for example: 1 of 10 pages, 2 of 10 pages ... 10 of 10 pages) and the order in which they should be read.

- A new statement “IF ANY LABEL INFORMATION IS MISSING, CONTACT THE MANUFACTURER/US/AGENT/DISTRIBUTOR BEFORE USING THIS PRODUCT” be added in capital letters to the principal display panel of the container label and/or the attached booklet.

3.2 Readability

The United States Environmental Protection Agency recognizes in its *Label Review Manual* that certain specialty products pose a challenge to meeting the regulatory labelling requirements. For containers that are too small to contain all the required label text, the manual states that it is permissible to have text located on accompanying pamphlets, which are considered labelling. Whatever the approach, all labelling must accompany the product at the point of sale, and the container must bear a statement referring the user to the location of any additional labelling that is securely affixed to the container.

The PMRA is proposing to require that:

- Under normal use, peel-back labels must be readable without turning the container upside down or sideways.
- A pictogram or line drawing is added to identify how to open the resealable label for further product information.

Suggested examples of acceptable pictograms and drawings that clearly identify the location of information on peel-back labels are provided in Appendix III.

3.3 Visibility of Safety Information

The PMRA is proposing to require the precautions or first aid on the secondary display panel of a peel-back label be:

- permanently affixed to the product container; or
- on the outer panel of the peel-back label.

If this information is permanently affixed to the container, the outer peel-back portion of the label must have instructions directing the user on how and where to open the peel-back label to obtain the safety information (see Section 3.2).

If the First Aid or Precautions text cannot be legibly printed on one panel, then this requirement could be waived.

4.0 Additional Requirements for Multi-component Labels

Some pest control products are packaged in small amounts, and these small containers have a limited amount of surface area available for labelling. To help meet the challenge of placing all required information on multi-component labels the PMRA has agreed, on a case-by-case basis, to allow registrants to move some information normally required on the principal display panel to the lower half of the secondary display panel. This includes:

- Guarantee statement
- Registration number
- Net contents
- Name and addresses of registrant and agent (mailing, internet or e-mail)

However, some registrants have requested moving even more information to the secondary panel, beyond what is currently permitted.

The PMRA is proposing that the following information be required on the principal display panel of all Domestic Class pest control products with multi-component labels.

- Product name
- Class designation
- Direction to read the label
- Child hazard warning
- Precautionary symbols, signal words and primary hazard statement

4.1 Symbols and Signal Words

Requirements for labelling of chemical products, other than pest control products, are described in Canada's *Consumer Chemicals and Container Regulations, 2001* and include certain exemptions for small and short, wide containers.

For short, wide containers on which the main display panel is less than 10 cm in height and at least twice as wide, the signal word may be located immediately beside the hazard symbol instead of below it.

The PMRA is proposing registrants be allowed, on the principal display panel of the product, to display signal words immediately beside any primary hazard symbols.

The Pesticides Safety Directorate *Labelling Handbook* in the United Kingdom describes the requirements for the presentation of information on labels and the acceptable minimum size of symbols displayed on them and outlines two exceptions for labels of small containers. For small containers with a capacity of three litres or less, the dimensions of the label should be at least 52 mm by 74 mm and the symbols at least 20 mm by 20 mm. However, if it is impractical to comply with these label dimensions then the label should be as large as possible. In any case, the symbol with background must not be less than 10 mm by 10 mm.

The PMRA is proposing to require the principal display panel of small container labels to have hazard symbols, including background, to measure a minimum of 10 mm by 10 mm.

4.2 Legibility

In the Final Rule of the Food and Drug Administration, United States Department of Health and Human Services, a label is considered too small if the information required on the principal display panel requires more than 60 percent of the total surface area available. The Final Rule describes ways to accommodate all the required information on small drug labels.

The PMRA is proposing to allow the following measures when information required on the principal display panel requires more than 60 percent of the total surface area available:

- the letter height and type size for headings be a minimum of 5 point (1.7 mm), and be emphasized in bold or underline
- leading space between two lines of text be a minimum of 0.5 point (0.17 mm) provided the letters do not touch
- bulleted statements continue to the next line of text if more than one bulleted statement is placed on the same horizontal line
- bullets under each heading or subheading not be vertically aligned

5.0 Implementation of Label Amendments

These additional requirements for peel-back labels are proposed to come into effect on 1 January 2010. After this date, submissions for new product registrations, amendments or registration renewals for currently registered products with peel-back or multi-component labels will not be completed unless those labels conform to the above requirements. Registrants will need to submit an application form, fee form, the appropriate fee, and a draft label to formally document the label change. After 1 January 2010, labels identified as lacking the required changes during the renewal process will not have their registration status extended and may be subject to compliance action.

References

Consumer Chemicals and Containers Regulations, *Hazardous Products Act* 2001 (SOR/2001-269), Department of Justice Canada.

Food and Drug Regulations (C.R.C., c. 870), *Food and Drugs Act* (R.S., 1985, c. F-27), Department of Justice Canada.

Over-The-Counter Human Drugs; Labelling Requirements; Final Rule. Food and Drug Administration, Department of Health and Human Services. *Federal Register* Vol. 64, No. 51 March 17, 1999.

Pest Control Product Regulations (SOR/2006-124), *Pest Control Products Act* 2002, Department of Justice Canada http://laws.justice.gc.ca/en/showtdm/cr/SOR_2006_124.

United Kingdom, Pesticides Safety Directorate, 2002 (amended 2004). *The Labelling Handbook*

United States Environmental Protection Agency, *Label Review Manual 3rd Edition*, Office of Prevention, Pesticides & Toxic Substances. EPA735-B-03-001, August 2003.

Appendix I Glossary of Terms

Approved text label: A label that meets the conditions of registration relating to the label as specified by the Minister and that is placed in the Register.

Display panel: The part of the label that is affixed to the container, wrapping, covering or holder in which a pest control product is wholly or partly contained, placed or packed. It does not include any brochure or leaflet that accompanies the product.

Label: Anything that conveys information that is required by this Act or the regulations to accompany a pest control product. Includes stickers, tags, seals, leaflets, brochures and wrappers applied on or attached to the control product package, and on which is written, printed, stencilled, lithographed or embossed any graphic matter that is descriptive or relates to the control product in any fashion.

Marketplace label: A label that matches the approved text label and that has added to it graphic designs or symbols that relate to the pest control product.

Multi-component label: A set of labels that meets the conditions of registration relating to the product's physical size or design. They contain multiple components such as container label, booklet, water soluble packet or outer packaging.

Peel-back label: A marketplace label that matches the approved text label, but has had some information placed on the inside panel of a multipage secondary panel.

Principal display panel: That part of a label displayed or visible under normal conditions of display for sale.

Secondary display panel: That part of a label other than the principal display panel.

Appendix II Criteria for the Use of a Peel-back or Multi-component Label

A product label that meets the following criteria, may become subject to the peel-back and multi-component label directive:

- When the regulatory required information on the label requires more than 60 percent of the total label surface area available.

and

- When the label is the largest allowed by design of the container and at least of the following minimum sizes:

Minimum Label Sizes for Various Net Content Containers

Container capacity	Dimensions of Label
3 litres or less*	not less than 52 × 74 mm*
exceeding 3 litres but less than 50 litres	not less than 74 × 104 mm
exceeding 50 litres but less than 500 litres	not less than 105 × 148 mm
exceeding 500 litres	not less than 148 × 210 mm

* If it is impractical to comply with the dimensions for this pack size, the label should be as large as possible, occupying a minimum of 40 percent of the available surface area of the pest control product container.

Appendix III Examples of Acceptable Pictograms and Line Drawings for Peel-back Labels

These examples are not the only pictograms that would be acceptable. The pictogram or indicator must clearly show that the label continues on behind the display panel.

